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October 26, 2018

Susan Edwards
Office of the Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

Genentech appreciates the opportunity to submit comments in response to this Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP. Genentech is a leading biotechnology company that discovers, develops, and manufactures novel medicines to treat patients with serious and life-threatening medical conditions. We are committed to helping patients access needed medicines and have a robust track record of program integrity.

Over the past year we have engaged with the Administration to help deliver drug payment solutions that will leverage private market competition for the benefit of Medicare beneficiaries and taxpayers, while maintaining access to appropriate medicines to improve patient care and outcomes. Genentech is committed to compliance with the federal anti-kickback statute (AKS), and shares the OIG's goal "to foster arrangement that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse."[1]

As we explain below, we urge the OIG to modernize its policies and safe harbors to facilitate the delivery of high value care. Our comments and recommendations focus on two main areas: value-based arrangements and patient support activities. Below is the outline of our comments.

I. **Value-based arrangements:** We urge the OIG to modernize existing safe harbors and develop new safe harbors to protect patients and the government from fraud and waste, support the development of creative pricing models, and improved access to innovative treatment paradigms to foster enhanced patient outcomes.
    A. Creation of a new safe harbor for value-based arrangements
    B. Creation of a new safe harbor for demonstrations authorized by CMMI
II. **Patient support activities:** We urge the OIG to establish safe harbors to protect various types of patient support activities that foster access to care and optimize treatment effectiveness.
    A. Creation of a limited safe-harbor protection for medication adherence support

[1] 83 Fed. Reg. 43608.

B. Creation of a safe harbor to allow manufacturers to provide reasonable cost-sharing subsidization in federal programs, when such assistance meets specific requirements

III. **Complementary regulatory changes:** We urge OIG to work with companion agencies to enable meaningful adoption of value-based arrangements, medication adherence and appropriate cost-sharing

We thank OIG for recognizing that health care delivery and payment models are evolving and for its interest in modernizing the AKS safe harbors to protect innovation that advances high value, patient-centered care. Although not the only changes needed to facilitate value-based care, AKS safe harbor reforms are crucial to improving access to innovations, that might be inadvertently disincentivized in our current payment and delivery models. If structured as suggested, such safe harbors will help patients covered by both public and commercial payers to realize the value of new payment models and treatment paradigms and the potential for enhanced outcomes.

We also want to highlight and applaud the approach that other HHS agencies, like FDA and CMS, are taking to put the needs of patients first as the health care system evolves. For example, we appreciate FDA's recent guidance on communications with payors and providers regarding health care economic information and communications consistent with the FDA label.[2] We encourage FDA to continue to support open discourse with payors and providers around unique payment and reimbursement structures, and for the OIG to ensure alignment with FDA around these standards. Likewise, we appreciate the approach that CMS has taken to address some of the areas highlighted by the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*[3], especially for Medicare beneficiaries.

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I. Value-based arrangements: We urge the OIG to develop new safe harbors to protect patients and the government from fraud and waste, support the development of creative pricing models, and improve access to innovative treatment paradigms to foster enhanced patient outcomes.

BACKGROUND

<u>Benefits of value-based arrangements</u>

In today's health care marketplace, payors expect manufacturers to demonstrate the clinical and financial benefits of their medicines and to share the financial risks associated with a new drug's performance. Value-based arrangements (VBAs) link a pharmaceutical product's net cost to its ultimate value in treating patients and are intended to reward a product's value (as measured by agreed-upon metrics such as improvements in specific patient outcomes or reductions in system costs), and require manufacturers to take accountability for their products by accepting financial risk if the products do not demonstrate their value in real world settings. Establishing these arrangements typically involves data-driven negotiation between sophisticated parties. Genentech has been a leader in implementing value-based arrangements; we have executed several arrangements using a variety of methods in the US (e.g., indication-based pricing, regimen pricing, and outcomes-based contracts).

VBAs advance the goal of shifting to purchasing methods that pay for value rather than volume of care and will help broader the available information concerning the effects of treatment regimens on different patient populations. VBAs may also expand patient access to appropriate new treatment options and ultimately improve patient outcomes. VBAs make manufacturers accountable for

2 FDA. Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Q&A, at 3.

3 https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/pdf/2018-10435.pdf

the real world results of their products and may reduce a payor's financial risk for therapies that prove ineffective in treating its beneficiaries.[4] Additionally, these types of arrangements may help improve access to breakthrough medicines for rare diseases with small patient populations or treatments that do not conform to traditional paradigms (e.g., personalized therapeutics, curative treatments, genetic or genomic-based treatments, etc.). For example, increasingly biomarkers and genetic information have become a key component for providers to determine the therapy and dosage most likely to benefit a patient; our system should encourage, not discourage, appropriate use of diagnostics and services that provide such information.

VBAs also have the potential to reduce costs for patients and the health care system. For example, a recent PhRMA study found that from 2015 to 2017, patient copays were 28 percent below the market average for certain plans that announced a VBA.[5] In a review of outcomes-based contracts, Avalere Health found that approximately three out of four payors engaged in these contracts experienced cost savings.[6]

Anti-kickback statute uncertainty is a barrier to implement VBAs

Genentech's primary focus on the development of VBAs is to improve patient care and outcomes and lower overall system costs. While we believe that VBAs can be structured to comply with the existing AKS safe harbors, the pharmaceutical industry's ability to embrace innovative arrangements is limited by these provisions that were adopted decades ago and do not specifically contemplate VBAs or innovative approaches that might better align with the novel types of therapies under development (e.g., regimens, personalized and tailored treatments, cures, genetic therapy). The lack of clear guidance, potential for significant penalties, and the Administration's proposal to reform the discount safe harbor to remove rebate protections[7] creates uncertainty as to how to apply the existing legal framework and results in substantial time and resources being dedicating to managing that uncertainty -- resources that might be better spent supporting patient access in other ways.

The Discount Safe Harbor should be modernized to adequately protect value-based and other novel arrangements

The discount safe harbor should contemplate that fraud and abuse risks are not uniform across all purchasers in the healthcare marketplace. Payors have financial incentives to encourage the use of treatment options that are less costly and/or more effective than alternatives. Accordingly, the risk of VBAs with payors encouraging product overutilization is low given this incentive structure, especially where safeguards that promote transparency to the government are in place.

VBAs often have requirements beyond the purchase of the product. VBAs often include a performance component (such as the payor reporting certain outcomes or determining whether patients who are taking a certain drug are meeting adherence criteria, or the net cost hinges on its clinical or cost

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[4] As VBAs expand the evidence available on how different treatments affect patients with a certain disease (or subgroups of patients with a certain disease) and how different products affect overall costs for treating particular diseases, physicians and patients will have the opportunity to make better-informed and more individualized treatment decisions and payors will be able to make better-informed and potentially more tailored decisions about formularies and coverage policies. *See* Deloitte, Value-based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value 8 (2012), *available at* http://www.converge-health.com/sites/default/files/uploads/resources/white-papers/valuebasedpricingpharma_060412.pdf.

[5] PhRMA, Delivering Results for Patients: The Value of Value-Based Contracts (Feb. 2018).

[6] Avalere Health. Press Release, Health Plan Interest in Outcomes-Based Contracts Increasing (July 12, 2018), *available at* http://avalere.com/expertise/life-sciences/insights/health-plan-interest-in-outcomes-based-contracts-increasing

[7] 83 Fed. Reg. 22692, 22698 (May 16, 2018).

performance for an individual patient or patient population covered by the payor).[8] Performance may be measured through clinical endpoints, avoidance of certain outcomes (e.g., hospitalizations), or overall costs associated with treating the patient's condition. Typically these agreements have complicated administrative requirements and require significant data collection and analysis activities, such as tracking patient outcomes and adherence to prescribed medication regimens. While the discount safe harbor itself does not limit a seller or offeror's ability to condition discounts on certain performance requirements (nor does anything in the safe harbor's regulatory history suggest such a limit), recent enforcement actions and public statements by federal prosecutors have generated confusion about the circumstances in which discounts may be conditioned on performance, or more than the purchase of the product, by the recipient.

"Reimbursement under the same federal healthcare program, using the same methodology" may inhibit VBAs. The discount safe harbor excludes bundled discounts unless (among other things) the goods and services are "reimbursed by the same federal health care program using the same methodology," however, the OIG has not specified what it means for a product to be reimbursed "using the same methodology" outside of the DRG setting.[9] We contend that rather than encouraging inappropriate use, allowing pricing to reflect the total goods and services associated with a particular therapeutic approach promotes more targeted and hopefully effective therapy.[10] Yet, the absence of guidance creates uncertainty regarding VBAs involving products used in different procedures or different settings, reimbursed under different federal programs, such as Medicare Part B and Part D, or where the manufacturer proposes to pay for ancillary items and services and could have the perverse effect of increasing costs but discouraging appropriate net pricing.

The discount safe harbor may not squarely protect arrangements with cost-reporters, such as hospitals, where the discount or rebate depends on longer-term patient outcomes. The discount safe harbor requires that a cost-reporting buyer must earn a discount "based on the purchases of that same good or service bought within a single fiscal year of the buyer" and the buyer must "claim the benefit of the discount in the fiscal year in which the discount is earned or the following year."[11] A true commitment to long-term improved patient care, may require arrangements that last more than a year. For instance, instance in a capitation or a subscription model, a payor makes a certain payment for a drug over a specified period (e.g., per quarter or per year) regardless of the number of patients using the drug or the amount used, giving payors financial certainty and an incentive to facilitate appropriate access. Medicare, in particular, has a unique ability to follow patients year after year, not only to measure improved outcomes and measures of efficacy, but to inform whether value is being added to the marketplace overtime.

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[8] Outcomes-based agreements may also involve manufacturers replacing their product for free or paying for additional therapies required when the product does not result in the agreed-upon outcomes. Andrew Pollack, Drug Deals Tie Prices to How Well Patients Do, NY Times, Apr. 22, 2009, *available at* http://www.nytimes.com/2009/04/23/business/23cigna.html.

[9] 42 C.F.R. § 1001.952(h)(5)(ii).

[10] VBAs account for the product's ultimate value in a patient's treatment (which may involve multiple therapies or ancillary services, differential pricing based on indication, or a set price for a product over a certain time period regardless of the dose required), therefore such arrangements potentially could involve discounts, on several items or services associated with the patient's care. VBAs could also encompass a bundled price for a clinically-proven end-to-end treatment -- for example, diagnostics, labs, the manufacturer's medication or intervention, the physician administration, ancillary supplies, and any follow up services. Such a model recognizes that access to services beyond the medication itself are often critical to patients achieving optimal health outcomes.

[11] 42 C.F.R. § 1001.952(h)(1)(ii).

RECOMMENDATIONS

A. Creation of a new safe harbor for value-based arrangements

Agreements between manufacturers and payors or risk-bearing organizations should have specific protections. Contracting parties should have the flexibility to define value in a way that is relevant to disease state and product, and these parties are in a position to do so because of their mutual incentive to improve outcomes and appropriately allocate related financial risk.[12] A VBAs safe harbor should protect arrangements between product manufacturers and payors or sophisticated, risk-bearing providers such as integrated delivery networks, and this should have a lower risk of fraud and abuse because these entities: (1) are incentivized to lower a patient's total health care costs; (2) have the expertise, experience, and resources to analyze data on clinical and cost outcomes from healthcare interventions in a rigorous manner; and (3) are focused on formulary management and/or coverage and reimbursement decisions on a population basis, rather than individual prescribing decisions.[13]

Value-based arrangements should not be restricted to a single product or service and should be allowed to include multiple items/services without limitation by the current reimbursement methodology or whether the entity is the manufacturer, supplier or provider. A value-based safe harbor should also provide flexibility with respect to the items and services covered by the arrangement and this flexibility will allow the new safe harbor to be durable over time as the healthcare system continue so to develop more personalized treatments like CAR-T therapies or curative treatment that require genotyping or other diagnostic prework.

A value-based safe harbor should protect parties that perform activities necessary to implement the arrangement, such as: (1) data collection and analysis, (2) adjudication of outcomes in circumstances where there may be a dispute, and (3) appropriate activities to promote adherence to patients' prescribed treatment regimens, so patients can get the best results from the product, reductions in other healthcare costs can be demonstrated, and non-adherence can be measured.

A value-based arrangement safe harbor should not contain time limitations. Specifically, the safe harbor should not require that an arrangement be in place for a particular period of time (e.g., one year) so that stakeholders have the ability to pilot new arrangements, track results over time and modify or end those arrangements where the intended results are not achieved. Additionally, the safe harbor should not require that a value-based payment occur within a certain time period. Many VBAs are longitudinal, tying payment to a longer-term patient outcome that might not be known to the parties for a number of years.

If the OIG is concerned about tracking reimbursement over time, it could also consider requiring that VBAs be structured to generate real world evidence demonstrating that the treatment improves health outcomes and/or lowers health care costs in a variety of patient populations that would be useful to patients, prescribers, and payors. Adding further information on product outcomes also could spur increased competition in relevant therapeutic areas and thereby drive down costs. Lastly, although VBAs offer important benefits to patients and the health care system, they are often very complicated. Thus, we urge the OIG to refrain from imposing safe harbor requirements that could introduce additional operational challenges to these already complex arrangements.

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[12] "Value" could include, among other qualities, improved adherence to treatment regimens, improved health outcomes, incremental cost savings to patients and/or the health care system, and enhanced patient access.

[13] 42 C.F.R. § 1001.952(h)(1)(ii). . As the FDA recently recognized, payors are well-suited to make these types of determinations, as they are a "sophisticated audience" that generally "possess[es] financial resources and motivation to closely scrutinize information about medical products as part of their decision-making process, including an evaluation of the limitations and reliability of that information" and this scrutiny helps support product selection, formulary management, and coverage and reimbursement on a population basis.

B. Creation of a new safe harbor for demonstrations authorized by the Center for Medicare and Medicaid Innovation (CMMI)

CMMI was created to test and benefit from the innovative reform efforts widely used in the private sector to develop quickly adjustable models that improve care, lower costs, and better align payment systems and incentives to support patient-centered practices in Medicaid, Medicare, and Children's Health Insurance Program (CHIP). To support this effort, Congress provided HHS with the authority to expand, or limit, the scope and duration of a model being tested through rulemaking, including the option of testing on a nationwide basis. In order for HHS to exercise this authority, a model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits. CMMI, on behalf of HHS, can use various authorities to conduct demonstration projects, including waiver of select statutory requirements, including waiver of certain methods of payment, including Best Price calculation requirements under Section 402 of the Social Security Act, and waiver of the AKS under Section 1115A of the Social Security Act.

Currently, CMMI's effort to create models with broad applicability have curtailed nimble testing of creative arrangements in care delivery and payment. Because the waiver eligibility requirements are nebulous and require parallel approval tracks, there appears to be understandable reticence on the part of both manufacturers and CMMI in moving forward with smaller and more targeted arrangements that would require both types of waivers to be viable. By creating a companion safe harbor to this already existing grant of authority, the OIG could help catalyze the submission of more proposals to CMMI, who then may be encouraged to test more innovative approaches and new structures. We recommend that the OIG promulgate a specific safe harbor exempting duly approved CMMI demonstration projects from anti-kickback liability. The alignment of an OIG safe harbor consistent with CMMI's delegated authority could lead to more demos with limited scope, creating broader industry engagement to foster value creation. Instead of taking a one-size-fits-all approach, smaller and more frequent demos would allow both CMMI and the participants to iterate on programs that work, abandon those that do not, allow comparative assessments of cost savings across multiple models, and promote experimentation in a variety of therapeutic areas that may be ripe for alternative payment models but for different reasons. In this way, the OIG would be helping HHS to fulfill its Congressional mandate to improve care, lower costs, and better align federal payment systems.

II. Patient support activities: We urge the OIG to establish safe harbors to protect various types of patient support activities that enable access to care and optimize treatment effectiveness

BACKGROUND

<u>Benefits of medication adherence programs</u>

Manufacturer-sponsored patient support offerings can improve patient quality of care, by increasing access to prescribed medications and necessary screenings and services, while optimizing the effectiveness of such treatments.[14] It is well-established that non-adherence is a significant health problem, leading to poor clinical outcomes and increased healthcare spending. Failure to take medications as prescribed causes an estimated 125,000 deaths a year and up to 10 percent of all

[14] For example, patients may benefit from assistance with adhering to prescribed medication regimens, drug administration training (for patient-administered products), disease education and side effect management, and supplies designed to ensure that a medicine is administered in a safe and effective manner. Patients may also face other treatment-related access barriers, including, providing access to diagnostic or lab testing or infusion services, or affording costs associated with a treatment, regimen or episode of care. As medicine becomes more targeted and personalized, the need for testing prior to or during the course of treatment is becoming increasingly common to help ensure that the product is working well for the patient and patients are getting the correct dose.

hospitalizations.[15] Medication adherence is particularly important to a broad range of serious chronic conditions, including cancer,[16] multiple sclerosis,[17] HIV/AIDS,[18] and ophthalmic conditions.[19] When chronic conditions are not well-managed, patients may face costly, avoidable complications and reduced ability to carry out daily activities and quality of life. As the number of Americans with chronic disease increases, the need to address this issue becomes more pressing.[20]

In addition to being good for patients and the health care system more broadly, medication adherence is a vital component of many VBAs. For instance, for outcomes-based arrangements, adherence is critical for ensuring that the measured outcome reflects the effects of the medication, as opposed to non-adherence of that medication.

Current barriers to implementing medication adherence activities that optimize treatment effectiveness

The OIG has provided limited guidance to manufacturers on medication adherence programs. The little guidance focuses primarily on a program's potential value to providers, rather than to patients. In particular, the OIG has stated that product support services "that have no substantial independent value to the purchaser may not implicate the anti-kickback statute," but an arrangement *would* raise kickback concerns "if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on the referring provider."[21] The few relevant OIG advisory opinions are fact specific and do not address scenarios reflecting advances in medicine, or the data demonstrating the value of compliance with a treatment regimen over the last decade.[22] Additionally, while the OIG has promulgated certain exceptions to the beneficiary inducement statute that reflect to some extent the new realities of patient-centered care,[23] the beneficiary inducement statute has limited applicability to manufacturer-sponsored programs and, therefore, has a chilling effect on manufacturer's ability to support patients for optimal care.[24]

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15 Meera Viswanathan, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review*, Ann Intern Med.* 2012;157(11):785-795.

16 Zafar, et al., Financial Toxicity, Part 1: A new Name for a Growing Problem, Oncology (February 2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4523887/.

17 Brittany Gerber et al., The Impact of Treatment Adherence on Clinical and Economic Outcomes in Multiple Sclerosis: Real World Evidence from Alberta, Canada, 18 Multiple Sclerosis and Related Disorders 218-224 (2017).

18 CC Carpenter, DA Cooper, MA Fischl, JM Gatell, BG Gazzard, SM Hammer, et al. Antiretroviral therapy in adults: updated recommendations of the International AIDS Society - USA Panel. JAMA 2000;283:381–390; Durant J, Clevenbergh P, Halfon P, Delgiudice P, Porsin S, Simonet P, et al. Drug-Resistance Genotyping in HIV-1 Therapy: the VIRADAPT Randomised Controlled Trial. Lancet 1999;353:2195–2199.

19 Christoph Ehlken et al., Association of Treatment Adherence with Real-Life VA Outcomes in AMD, DME, and BRVO Patients, 12 Clinical Ophthalmology 13-20 (2017).

20 Chronic diseases affect approximately 133 million Americans, representing over 40% of the population. Centers for Disease Control and Prevention. The Power of Prevention. (2009), *available at* http://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf. By 2020, the number of Americans with chronic diseases is projected to increase to approximately 157 million. Tackling the burden of chronic diseases in the USA. Lancet 2009;373 (9659):185, *available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)60048-9/fulltext.

21 OIG, Compliance Program Guidance for Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

22 *See*, *e.g.,* Adv. Op. 11-07 (finding a low risk of abuse for a vaccine reminder program); Adv. Op. 08-05 (concluding that kiosks in physician offices that printed a patient's answers to a questionnaire would not provide anything of value to patients); Adv. Op. 07-16 (finding that a home health agency's provision of free educational videos had no significant value to patients and was unlikely to influence their selection of a home health agency); Adv. Op. 00-10 (finding that insurance coverage criteria information for a manufacturer's products had "no independent value to providers, was properly considered included in the products' price.).

23 42 C.F.R. § 1003.110; 42 C.F.R. § 1003.101. .

24 The beneficiary inducement statute applies to incentives to obtain Medicare- or Medicaid–reimbursed items or services from a "particular provider, practitioner, or supplier," and pharmaceutical manufacturers generally are not considered "providers, practitioners, or suppliers" under this statute. SSA § 1128(a)(5).

These support activities are important to patients' health outcomes and they are provided in conjunction with an already prescribed product, limiting the potential for abuse and effectively constitute a part of the reimbursable product(s) to which they relate. Nonetheless, the lack of clarity regarding what constitutes permitted, limited support and the absence of safe harbors to protect these beneficial, low-risk arrangements has a chilling effect on these offerings -- which can be crucial to help patients get the best possible results from their prescribed treatments.

High patient cost-sharing is a barrier to high value care

Enrollees in federal programs often face significant cost-sharing, particularly those patients with complex, progressive, and chronic diseases. The Medicare program provides health care coverage for 59 million people, approximately 18 percent of the US population, but does not include protections against catastrophic health care costs.[25] In 2016, Medicare beneficiaries with chronic disease or disability spent an average of $5,519 per year compared to $1,549 for those without; and nearly one-third (29 percent) of beneficiaries with three or more chronic conditions and 38 percent of beneficiaries with physical and/or cognitive limitations spent 20 percent or more of their annual incomes on premiums and cost-sharing for medical care.[26]

High cost-sharing can be a significant barrier to treatment and result in suboptimal or low-value care. Due to the Part D benefit design and plan treatment of specialty drugs, Part D beneficiaries, who do not qualify for the program's low-income subsidy (LIS) are often required to pay over $1000 dollars for the first fill of a medicine to treat debilitating and progressive diseases such as cancer, respiratory diseases, rheumatoid arthritis, multiple sclerosis, among others. Recent research into cost-sharing and the Part D benefit shows that the high cost-sharing associated with this program is associated low adherence with prescribed treatment.

- **Abandonment of care:** When patients face more than $100 in cost-sharing abandonment rates -- patients not starting on prescribed treatment -- increase significantly.[27,28]
- **Reductions and delays in treatment initiation following a new diagnosis or disease progression:** Non-LIS cancer patients facing high cost-sharing for an initial fill (~$2600) are less likely to fill prescriptions and have longer delays when they do fill prescriptions.[29,30]
- **Delays between refills or treatment interruptions:** Receipt of the LIS was associated with a significantly higher probability of receiving the standard of care regimen use to treat multiple myeloma and a significantly lower risk of delays between refills.[31]
- **Earlier discontinuation of treatment:** Beneficiaries not receiving low-income subsidies who faced high cost sharing for psoriasis were nearly twice as likely to discontinue treatment compared to beneficiaries receiving low-income subsidies through Part D.[32]

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[25] CMS Fast Facts. Population, 2016-2018. Accessed: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html

[26] Schoen K, Davis K, Willink A. Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status. Commonwealth Fund. May 2017. Accessed: https://www.commonwealthfund.org/publications/issue-briefs/2017/may/medicare-beneficiaries-high-out-pocket-costs-cost-burdens-income

[27] Doshi JA, Li P, Huo H, et al. Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. J Clin Oncol 36:476-482.

[28] Gleason PP, Starner CI, Gunderson BW, Schafer JA, Sarran HS. Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. J Manag Care Pharm. 2009 Oct;15(8):648-58.

[29] Doshi JA, Li P, Huo H, et al. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia. Am J Manag Care. 2016;22(4 Suppl):S78-S86.

[30] Li P, Wong YN, Jahnke J, et al. Association of high cost sharing and targeted therapy initiation among elderly Medicare patients with metastatic renal cell carcinoma. Cancer Med. 2018 Jan;7(1):75-86.

[31] Olszewski AJ, Dusetzina SB, Eaton CB, et al. Subsidies for Oral Chemotherapy and Use of Immunomodulatory Drugs Among Medicare Beneficiaries With Myeloma. Journal of Clinical Oncology 35, no. 29 (October 10 2017) 3306-3314.

[32] Doshi JA, Takeshita J, Pinto L, et al. Biologic therapy adherence, discontinuation, switching, and restarting among patients with psoriasis in the US medicare population. J Am Acad Dermatol. 2016;74(6):1057-1065.e4.

Similar barriers to care exist for patients prescribed Part B medicines who do not have supplemental coverage (e.g., Medigap or employer sponsored insurance) to pay some or all of the 20 percent coinsurance required under the benefit. High cost sharing for drugs in the Medicare program may place patients at risk of compromised treatment outcomes due to reduced/delayed initiation, poor adherence, high discontinuation and/or interruptions in needed treatments.

It is difficult to quantify the negative health effects of high-cost sharing and associated non-adherence outcomes. However, once a patient is prescribed a medicine and an insurer agrees to cover it, if exorbitant cost-sharing discourages a patient from taking a prescribed medicine (as evidenced above), the value of care delivered is in jeopardy. While insurers often use cost-sharing as a way to incentivize use of a less expensive product, prohibitive cost-sharing for medicines included on a formulary contravenes the purpose of plan coverage decisions and policies. Additionally, there is a real economic cost to the system when patients do not receive prescribed medicines: in 2012, CBO determined that a one-percent increase in the number of prescriptions filled resulted in a reduction in medical spending by one-fifth of a percent. While decreases in medical spending are unlikely to offset increases in prescription drug spending completely, CBO's finding indicates that beneficiaries taking appropriate Part D medicines see tangible health effects resulting in lower medical spending.

RECOMMENDATIONS

A. Creation of a limited safe-harbor protection for medication adherence support

The OIG should promulgate an adherence support safe harbor like that recommended by Prescription for a Healthy America and discussed in the comments of the Biotechnology Innovation Organization (BIO) response to this Request for Information. This safe harbor should protect important adherence support activities that improve health outcomes while providing safeguards to prevent skewing clinical decision making, patient steering, inappropriate utilization, and increased healthcare program costs. Manufacturer support should only be offered after an independent clinical decision of medical necessity by the patient's health care provider, so such arrangements are unlikely to skew prescriber or patient decision-making and have low risk of fraud and abuse. To the extent these activities increase utilization, the increased utilization would be consistent with a patient's independently-prescribed treatment regimen and should thus be appropriate and could also serve to help monitor a patient's treatment to ensure that it is efficacious and correctly dosed. As noted above and in the extensive body of literature on adherence, it is also likely that improved compliance with a treatment regimen will lower overall health care costs by reducing avoidable complications of disease and thus reducing utilization of other expensive service.

Recognizing that not all products and programs may be good candidates for safe harbor protection, as an additional safeguard to ensure that the medication adherence safe harbor protects arrangements that improve adherence or patient outcomes, the safe harbor could condition protection on the collection and monitoring of data on adherence or outcomes related to the arrangement and require termination of the program if the data show that the specified measures are not being met. The safe harbor could further require the sponsor to provide data, at HHS' request, regarding the intervention's effect on adherence or patient outcomes.

B. Creation of a safe harbor to allow manufacturers to provide reasonable cost-sharing subsidization in federal programs, when such assistance meets specific requirements

The OIG should allow manufacturers to partially subsidize patient cost-sharing for prescription drugs in order to help alleviate patients' cost-sharing burden. If a program meets the following criteria it

would reduce risks of creating system waste and possible abuse, while helping patients afford needed medicines.

- **Maintain reasonable costs for prescribed medicines:** Complete subsidization of cost-sharing may not be appropriate. Federal programs and plans administering benefits should be able to use different levels of cost-sharing to incentivize cost-effective care; third party subsidization should not undermine this tool. To that end, HHS should determine a minimum cost-sharing amount required on a disease specific basis by reviewing available independent research. This minimum cost-sharing amount would be the amount left for the patient responsibility after third party subsidization to ensure patients continue to have "skin in the game" without cost-sharing being prohibitive. Note: Disease-specific cost-sharing is important because different disease states carry different types of medication needs (e.g., one course of therapy vs. chronic use) and will affect patients ability to pay. A recent review of the literature on cost-sharing for specialty medicines found that abandonment rates fell to ~5 percent when cost-sharing was below $50 for chronic diseases such as multiple sclerosis and rheumatoid arthritis and less than $100 for more acute courses of treatment.[33]

- **Demonstrate financial need:** Cost-sharing subsidization should only benefit patients who have a financial need. However, less than 10 percent of Medicare beneficiaries have incomes above $85,000 per year.[34] Data show that individuals with income below this level, but do not qualify for LIS, spend a disproportionate share of income on health related expenses.[35] As such, we believe it is reasonable to assume that all but those individuals who are charged an additional premium for Part B have a financial need when cost-sharing for a medicine is above an established "reasonable amount".

- **Maintain competitive, market-based dynamics via direct patient benefit:** Cost-sharing subsidization should not influence prescribing decisions or coverage decisions, and should not undermine competitive dynamics in the marketplace. To ensure that cost-sharing subsidization does not unduly influence these decisions or undermine market forces, patients would enroll directly with the third party and the third party would remit the assistance directly to the patient. This would ensure cost-sharing subsidization would only occur to help patients start on, or stay on, a therapy that the provider and payer have agreed is correct for the patient.

- **Create transparency:** The OIG may need to be able to track use of such programs to verify cost-sharing subsidization improves adherence and persistence, and as a result, outcomes. As such, the OIG could require third parties subsidizing cost-sharing to submit quarterly reports to the agency regarding use.

III. Complementary regulatory changes: We urge the OIG to work with companion agencies and congress to enable meaningful adoption of safe harbors for value-based arrangements, medication adherence and appropriate cost-sharing

In addition to addressing the challenges created by the AKS, we urge the OIG to work with its companion agencies within HHS and elsewhere in the federal government to address other legal and

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33 Doshi JA, Li P, Ladage VP, et al. Impact of Cost Sharing on Specialty Drug Utilization and Outcomes: A Review of the Evidence and Future Directions. Am J Manag Care. 2016;22(3):188-197.

34 Gretchen Jacobson, Shannon Griffin, Tricia Neuman, and Karen Smith. Income and Assets of Medicare Beneficiaries, 2016-2035. Kaiser Family Foundation. April 2017. https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/

35 Juliette Cubanski, Kendal Orgera, Anthony Damico, and Tricia Neuman. The Financial Burden of Health Care Spending: Larger for Medicare Households than for Non-Medicare Households. Kaiser Family Foundation. March 2018.

regulatory uncertainties that can limit VBAs and patient cost containment. Without complementary changes, the potential benefits VBAs and improved adherence could bring to patients and the healthcare system, would be needlessly limited -- even with the adoption of new AKS safe harbors. In particular, we encourage the OIG to coordinate with co-interested agencies in the following areas:

A. Additional regulatory regimes in need of modernization to foster value-based care

- **Government Price Reporting**: Government price reporting calculations, such as the "Best Price" component of the Medicaid rebate formula for brand drugs and the requirements concerning Medicare Part B average sales price (ASP) calculations, complicate and limit implementation of value-based agreements. The system is currently designed for unit-based volume pricing of pharmaceutical products. However, VBAs and other novel pricing structures operate outside the model contemplated by the government pricing reporting regime. For instance, manufacturers may be reticent to offer a warranty or significant rebate for poor outcomes in a case where a single poor outcome could set Best Price and thus affect the Medicaid rebate amount for all Medicaid utilization of that product. Government pricing rules also can frustrate variable or bundled pricing via VBAs, particularly where an arrangement might involve the manufacturer providing products for free or at a significant discount, or covering the cost of certain ancillary services. Current ASP-based payment rules also can create barriers to VBAs that involve indication-based pricing. To allow manufacturers to evaluate these types of value-based models without the (sometimes insurmountable) complexities introduced by government pricing requirements, HHS should use its existing authority to exempt price concessions provided under a VBA from government pricing calculations where possible.

- **Antitrust**: Arrangements that may involve combination therapies or bundled payments that require manufacturers to coordinate, raising uncertainty with respect to antitrust law. We recommend HHS work with the Federal Trade Commission (FTC) and the Department of Justice (DOJ) to craft specific antitrust guidelines regarding competitor collaborations in the context of VBAs (as FTC and DOJ have done in the context of Accountable Care Organizations).[36]

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA):** VBAs typically require the parties to longitudinally track and share patients' treatment and health status information as part of the process for validating a particular payment (e.g., whether a particular outcome occurred that would trigger a payment). This type of data sharing often requires that parties be able to validate a particular patient's use of a treatment and the outcome for that same patient. We believe that existing HIPAA exceptions that allow HIPAA-covered entities to disclose protected health information (PHI), including but not limited to exceptions for payment, health care operations, and de-identified data, cover most type of needed data sharing. Nevertheless, we recommend that HHS issue guidance confirming that these exceptions apply to the disclosure of PHI when such data are provided in order to facilitate a VBA.

B. Structural Changes to Medicare Benefit Design

We would also like to advance the following recommendations to modernize the Medicare benefit.

- **Create an out-of-pocket maximum for Medicare Part A and B:** Virtually all commercial insurance products, including Medicare Advantage, are now required to include an out-of-pocket

[36] Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011).

maximum to protect patients against catastrophic health care costs. However, fee-for-service beneficiaries are not provided the same protections. We recommend that CMS work with Congress, health policy experts, and affected stakeholders (including manufacturers) to determine an effective way to reduce cost-sharing burden for high need beneficiaries without undermining benefit design and creating unsustainable cost increases to the system.

- **Create an out-of-pocket maximum for Medicare Part D:** Similar to above, Part D beneficiaries are not protected against catastrophic health care costs. In 2016, 800,000 patients reach the catastrophic where they are still responsible for 5 percent cost-sharing.[37] While cost-sharing in this phase is lower than it is in earlier phases, an out-of-pocket maximum would help provide beneficiaries with certainty regarding their drug expenditures, potentially allowing them to budget for total annual costs.

- **Modernize cost-sharing obligation metrics in ways that reflect existing cost of innovation:** When the Part D drug benefit launched, most prescription products were small molecule, chemical compounds used to treat broad diseases. Today, many medicines are created from living cells, targeted to a patient's specific genetic makeup, and harness the immune system to manage disease. Today's specialty medicines are better able to manage chronic disease, which accounts for 90 percent of healthcare spending. However, improved outcomes, increased scientific complexity, and targeted patient populations paired with the inflexible Part D benefit create affordability issues. In 2006, at program inception, 25 percent cost-sharing may have seemed appropriate for a high cost, specialty medicine. However, today the sums patients are responsible for interfere with the ability for providers to treat patients effectively. Once a provider has prescribed a medicine and payer works with the provider to determine it the right medicine to cover, the patient should not face prohibitive cost-sharing. We urge HHS to study what cost-sharing level would be appropriate given the prescription drug ecosystem today and also consider ways to spread patients cost-sharing over time to improve affordability.

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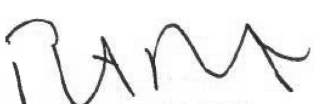
In closing, Genentech appreciates the Inspector General's attention to removing barriers to value-based care. Please do not hesitate to contact Brian Maloney, Director, Government Affairs, at maloney.brian@gene.com, if you have any questions about this response.

Sincerely,



Fritz Bittenbender
Senior Vice President
Government Affairs

[37] Dan Mendelson, Kelly Brantley, Richard Kane. More Medicare Part D Enrollees Are Reaching Catastrophic Coverage. Avalere. May 10, 2018. Accessed: http://avalere.com/expertise/life-sciences/insights/more-medicare-part-d-enrollees-are-reaching-catastrophic-coverage.